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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/390,740	02/17/1995	ROGER COLEMAN		7334

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EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/03/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/390,740	Applicant(s) Coleman et al.
	Examiner Ardin Marschel	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 10, 2002*

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *40-104* is/are pending in the application.

4a) Of the above, claim(s) *43-45, 48-51, and 55-104* is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *40-42, 46, 47, and 52-54* is/are rejected.

7) ☒ Claim(s) *1-39 have been canceled.* ~~are objected to.~~

8) ☒ Claims *40-104* are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Feb 17, 1995* is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Attachment for PTO-948*

NON-ELECTED SUBJECT MATTER

Newly submitted claims 61-104 are directed to inventions that are independent or distinct from the invention originally claimed and/or elected as summarized in the Office Action, mailed 12/28/95 (Paper No. 5), as well as the Office Action, mailed 4/23/01 (Paper No. 22), and as summarized below for newly submitted invention Groups VII - X, for the following reasons:

Said claims 61-104 set forth subject matter of non-elected Groups as follows, reiterated from said Paper No. 5 or regarding newly submitted invention groups:

Group III (methods of producing PANEC-1 and PANEC-2 polypeptides and said polypeptides) - claims 61, 67, and 76-78

Group IV (antibodies, immunoassays, pharmaceutical compositions and methods of treatment), which reasonably includes methods of making antibodies as practical only via animal immunization - claims 68-75, 80-99, and 101

Group V (agonist or antagonist screening; defined as a distinct Group in the Office action, mailed 4/23/01) - claim 104

New Group VII directed to inducing an immune response via polypeptide administration - claims 62-66, classified in Class 424, subclass 184.1.

New Group VIII, directed to a method of making a polynucleotide - claim 79, classified in Class 435, subclass 91.1.

New Group IX, directed to a method of purifying a polypeptide via antibody binding - claim 100, classified in Class 536, subclass 25.4.

New Group X, directed to a method of purifying a receptor for a polypeptide via polypeptide binding - claims 102 and 103, classified in Class 536, subclass 25.4.

Newly set forth restriction Groups are distinct for the following reasons:

The inventions of Group III versus Groups VII and X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the inventions of Groups VII and X are distinct methods of use directed to inducing an immune response (Group VII) and purification of a receptor via polypeptide binding (Group X) versus methods of treatment as in Group III already. The eliciting of an immune response requires distinct procedures including immunization steps with repeated challenge by a polypeptide as well as monitoring antibody production thereby compared to polypeptide treatment which would be monitored via disease or inflammation reduction. The purification of a

receptor utilizes affinity chromatography or related binding procedures which lacks any treatment or polypeptide administration to a patient etc. thus also being a distinct method over treatment methods. Thus, Groups VII and X are distinct and would require an undue search regarding distinct procedural steps in these Groups compared to Group III.

The inventions of Group I (Paper No. 5) and Group VIII are related as product made and a process of making, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the polynucleotides of Group I may be made by the distinct processes of nucleic acid chemical synthesis or via host cells as in Group VIII. These distinct methods of making require clearly different procedures as one is performed in chemical reactions, free of live cells and free of culturing, whereas the Group VIII method requires live cell culturing thus documenting the undue search burden for inventions which are clearly performed differently and non-overlapping in subject matter.

The inventions of Groups IV (Paper No. 5) and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody usage for polypeptide purification is not a required method for any of the Group IV uses which are directed to immunoassay or treatment methods therein which are completely different and thus distinct from affinity polypeptide purification as in Group IX thus documenting the undue search burden if these are searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicants have received an action on the merits for the originally presented and elected invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-104; as well as previously withdrawn claims 43-45, 48-51, and 55-60; are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

DRAWING OBJECTIONS:

Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on

the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 22 on 4/23/01. Due to this notification Applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title lacks correspondence with the presently claimed and elected invention. The lack of correspondence is present in that the present title, firstly, only cites one chemokine whereas two are claimed and elected, and secondly, the title is generic to a chemokine whereas specific chemokines are claimed and elected, directed to human eotaxins, or, alternatively, PANEC-1 and PANEC-2.

RESPONSE TO APPLICANTS' ARGUMENTS AND AMENDMENTS

Applicants' arguments, filed 10/10/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete

set presently being applied to the instant application.

NEW MATTER

Claims 40-42, 46, 47, and 52-54 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly submitted limitations in the claims directed to "a naturally-occurring amino acid sequence 90% identical to an amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4" has not been found as filed nor pointed to by applicants. It is noted that applicants pointed to Example IV in the specification for support. Consideration of said Example IV, as well as the entirety of the remainder of the instant specification, claims, and abstract, as filed, has failed to reveal any written basis for the numerical value of 90%, nor that naturally-occurring sequences are inclusive of variants from SEQ ID NO: 2 or 4, nor even that naturally-occurring sequences fall within a 90% identity difference range compared to SEQ ID NOs: 2 or 4.

SCOPE OF ENABLEMENT REJECTION

Claims 40-42, 46, and 47 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while providing written description enablement SEQ ID NOs: 1 and 3, does not

reasonably provide written description enablement for genomic sequences etc. as summarized below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

This rejection is reiterated and maintained from the previous office action, mailed 6/6/02, as the specification fails to provide written description for genomic sequences, etc. as summarized below. The following reasoning is repeated followed by a response to arguments of applicants, filed 10/10/02.

The specification discloses SEQ ID NOs: 1 and 3 which correspond to the cDNA encoding the PANEC-1 and PANEC-2 protein species, respectively. It is noted that cDNA cloning resulted in elucidating said SEQ ID NOs: 1 and 3 as given in the instant specification on pages 15-16, but that section V on page 17 lacks disclosure of a full length gene sequence. SEQ ID NOs: 1 and 3 per se meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the above listed claims are directed to encompass full gene sequences, sequences that hybridize to SEQ ID NOs: 1 or 3. None of these genomic sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Applicants previously argued that the instant claims do not

include claiming of any genomic sequences. In response, the claims include a scope which does, in fact, include such genomic sequences as encoding amino acid sequences and therefore enabling disclosure is necessary to overcome this rejection. Applicants also previously argued that a sequence encoding an amino acid sequence is limited so as to exclude genomic sequences and that such genomic sequences are well known to not be directly translated into proteins. In response, there is no instant claim limitation that requires that the claimed polynucleotide sequences must be directly translated into protein. Rather the limitation in parts a) and b) of claim 40 broadly state that the claimed polynucleotides encode an amino acid sequence. Applicants further argued that, even if the claim wording encompasses an unspliced or incompletely spliced polynucleotide sequence then the hypothetical polypeptide would merely be an artifact or that an intron would comprise a nonsense sequence. In response firstly the claim wording is inclusive of often utilized and well known wording in the art to include genomic sequence. Three example Patents were cited wherein genomic polynucleotide sequence is stated as encoding protein even including the presence of introns and exons where appropriate splicing is needed to obtain the mature mRNA for translation. See, for example, Campbell et al.(P/N 5,672,694) at column 3, lines 13-25, describe nucleic acids which encode the protein β-

sacoglycan as including intron-containing genomic DNA sequences. In Campbell et al.(P/N 5,733,732) in column 3, lines 32-39, a genomic DNA library contains clones which encode an adhalin gene. Primers are utilized for PCR amplification which specifically hybridize to intron sequences that flank an exon in order to amplify the exon sequence. Lastly, Liu et al.(P/N 5,837,457) at column 3, lines 10-22, Liu et al. clearly defines a gene or nucleic acid which is either genomic or synthetic which encodes a protein product. Thus, wording regarding encoding a polypeptide or protein as utilized in the instant claims are clearly also utilized frequently in the related art such that a polynucleotide sequence or nucleic acid which encodes a protein or amino acid sequence is inclusive of genomic DNA which encodes said protein or amino acid sequence. Thus, the instant disclosure lacks written basis for polynucleotide sequences which are genomic even though claimed, thus supporting this rejection.

In applicants arguments, filed 10/10/02, the argument is set forth that the instant claims are directed to purified polynucleotide sequences which directly encode a claimed polypeptide. This "directly" encoding limitation is not present in any of the instant claims and thus this argument is non-persuasive as being unsupported by the factual basis of the claim wording. Applicants then argue that without disclosure of which sequences are intronic genomic sequences one cannot render the

claimed sequences obvious nor included within the scope of the polynucleotide claims. In response obviousness is not an issue or basis for this rejection, therefore the issue of obviousness or not is moot regarding this rejection. Further the scope of the presently worded polynucleotide claims do, in fact, include any polynucleotide sequence, including genomic sequence, which encodes a claimed polypeptide and it is acknowledged from applicants' argument that genomic sequence would include intronic sequences. It is thus agreed that such intronic sequences are not instantly disclosed and thus it is agreed with applicants that the scope of written basis in the instant disclosure lacks written support for such intronic and corresponding genomic sequences. Even if applicants were to submit claims which contain wording such as "polynucleotide which directly encodes a polypeptide", that this still would not overcome this rejection. This is because there is no instant definition as filed, nor art recognized definition, as to what is meant by "directly" regarding coding sequence. It may be reasonably expected that a host cell containing a cloned genomic sequence, under appropriate conditions, may properly process such a sequence into mature mRNA which then would be translated into a polypeptide. The growth of such host cells in cell culture, for example, reasonably may be viewed as "directly" expressing the cloned genomic sequence into a polypeptide in said cell culture, albeit by multiple steps,

such as transcription, mRNA maturation, and translation into protein. It is not seen that "directly" is equivalent wording to a limitation directed to mature mRNA practice only, for example. In summary the only sequences per se that have written basis as filed for being utilized for the expression of PANEC-1 and PANEC-2 are SEQ ID NOs: 1 and 3.

PRIOR ART REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 40, 42, 46, 47, and 52-54 are rejected under 35 U.S.C. § 102(e)(2) as being clearly anticipated by Li et al.(P/N 6,518,046).

SEQ ID NO: 1 of Li et al. is a 405 base sequence which is

100% exactly the same regarding the first 402 bases as instant SEQ ID NO: 3. The remaining 3 bases of SEQ ID NO: 1 of Li et al. encode a stop translation codon. SEQ ID NO: 2 of Li et al. is a 100% match with the 134 amino acid sequence of the instant PANEC-2 polypeptide (instant SEQ ID NO: 4). It is noted that the issuance of P/N 6,518,046 makes the file for parent U.S. Application serial number 08/294,251 available for public consideration. The specification for 08/294,251 at page 7, first full paragraph, discloses a Deposited Biological material which contains a polynucleotide sequence therein disclosed as controlling in the event of any sequence conflict. It is noted that the copy of the Australian priority document, based on application serial number 08/294,251 also contains this controlling statement therein on page 7. A corrected sequence based on this Deposit was filed on Feb. 9, 1995; in serial number 08/294,251; which predates the instant filing date. Thus, in the circumstance of an Interference, it would be customary for Li et al. to be designated as Senior Party. Further, it is customary for the burden of filing the necessary statements and affidavit(s) under 37 CFR § 1.608(b) to be on the instant applicants, if desired. It is also noted that polynucleotide subject matter is a composition which may be sought to be patented, but that a sequence thereof is only a characterization. As such, a correction of sequence characterization of the

disclosure of a polynucleotide invention, for example Deposited in a Patent Depository, is generally permitted as the actual subject matter of the invention is the Deposited polynucleotide and not its sequence characterization per se. Applicants have submitted arguments that are non-persuasive regarding the sequence correction performed by Li et al. in parent U.S. Application No. 08/294,251. Thus, the record of the priority disclosure of Li et al. at present predates the instant claims and this rejection is deemed proper as based on prior art. Li et al. also discloses recombinant versions of eotaxin sequence as well as in host cells for expression with an appropriate promoter as set forth in column 6, line 50, through column 9, line 59. Detection via hybridization assay to probes made of sequence fragments, optionally using PCR amplification, is also disclosed in column 10, line 26, through column 11, line 28, as is instantly claimed.

SOME COMMENTS REGARDING SPECIFIC ART ANALYSES FOR REFERENCES SUPPLIED IN THE IDS, FILED 10/10/02.

RE: P/N 6,403,782 - It is acknowledged that a one base sequence difference exists between the instant SEQ ID NO: 1 and SEQ ID NO: 26 of P/N 6,403,782 and that the record indicates that even the earliest provisional filing date is after the instant application filing date, thus making the present record prevent a prior art type rejection. The argument pointing, however, to a

one base difference is confusing as applicants are claiming at present sequences inclusive of such a difference via instant claim limitations directed to 90% amino acid sequence identity for encoded polypeptides which includes a polynucleotide encoding a polypeptide with only one base difference and a corresponding one amino acid difference. It is noted that an interference proceeding is generally the appropriate procedure to resolve the issue of overlapping subject matter between an earlier filed application and an already issued Patent.

RE: US Patent Publication 2002026044, WO 96/05856 and P/N 5,981,230 - No matches which are close enough nor does P/N 5,981,230 claim any overlapping subject matter

RE: References discussed as PANEC-1 references 5-23 - No issues at present due to later dates of disclosure or publication, or, alternatively, Incyte assigned publication

RE: WO 96/06169 and U.S. Application serial Number 08/294,251 - See the above rejection under 35 U.S.C. 102(e)(2) based on Li et al.(recently issued 6,518,046) which is a 371 filing from PCT/US05/06260 (PCT application for WO 96/06169).

RE: References discussed as PANEC-2 references 5-23 - No issues at present due to later dates of disclosure or publication, or, alternatively, Incyte assigned publication

Certain IDS citations were lined through due to either a lack of a date of publication as required for citations on a PTO

Form 1449 or to avoid duplication of citation from another similar form.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 13, 2003

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER